UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR - 9 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: MAQUAT 86-M
EPA Registration Number 10324-85
Data Package D240658 (logged-in under Reg. No. 10324-80 by mistake; adjustment has been made)
Start Date 03/10/98

From: Wallace Powell, Biologist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510W)

Thru: Laura E. Morris, Team Leader
Risk Assessment and Science Support Branch
Antimicrobials Division (7510W)

Norman Cook, Chief 04/09/98
Risk Assessment and Science Support Branch
Antimicrobials Division (7510W)

To: Velma Noble, Product Manager, Team 31
Julie Fairfax, Team Reviewer, Team 31
Registration Branch I
Antimicrobials Division (7510W)

APPLICANT: Mason Chemical Company

TESTING LAB: Tox Monitor Laboratories, Inc.

FORMULATION:

Active Ingredients:	Percent by wt.	EPA PC Code
Octyl decyl dimethyl ammonium chloride	0.026	069165
Dioctyl dimethyl ammonium chloride	0.013	069166
Didecyl dimethyl ammonium chloride	0.013	069149
Alkyl (C_{14} 50%, C_{12} 40%, C_{16} 10%) dimethyl benzyl ammonium chloride	0.034	069105
Inert Ingredients:	99.914	

BACKGROUND. The registrant, Mason Chemical Company, has submitted a label amendment along with a Confidential Statement of Formula (for alternate formulation) and four acute toxicity studies, for the product MAQUAT 86-M, EPA Registration No. 10324-85, labeled as a liquid disinfectant, sanitizer, and deodorizer. The acute studies submitted are acute oral toxicity, acute dermal toxicity, primary eye irritation, and primary dermal irritation.

RECOMMENDATION

§81-1. Acute Oral: Toxicity Category IV (i.e., $LD_{50} > 5.0$ g/kg). The submitted study, MRID No. 444063-01, is acceptable.

§81-2. Acute Dermal: Toxicity Category III or IV (i.e., $LD_{50} > 2.0$ g/kg). Category III (defined as $2.0 \text{ g/kg} < LD_{50} \leq 5.0 \text{ g/kg}$) is being assigned for labeling purposes. The submitted study, MRID No. 444063-02, is acceptable.

§81-4. Eye Irritation: Toxicity Category IV (i.e., minimal effects, clearing in < 24 hours). The submitted study, MRID No. 444063-03, is acceptable.

§81-5. Dermal Irritation: Toxicity Category IV (i.e., mild or slight irritation). The submitted study, MRID No. 444063-04, is acceptable.

PRODUCT LABEL STATEMENTS

For the §81-1, §81-2, §81-4, and §81-5 hazards, the required precautionary and practical treatment statements listed below are based on the four submitted studies listed above. The absence of any statements below regarding inhalation or sensitization hazards (§81-3, §81-6) is based on the last accepted label. Note: all statements must appear under their respective headings.

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS UNDER THE "HAZARDS TO HUMANS AND DOMESTIC ANIMALS" HEADING:

Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

STATEMENTS UNDER THE "STATEMENT OF PRACTICAL TREATMENT" (OR "FIRST AID") HEADING:

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if symptoms persist.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Reviewer: W. Powell
Product No.: 10324-85
DP Barcode: D240997
MRID No.: 444063-01
Report No.: TM Study 97-99-3
Study Completion: 07/16/97
Study Director: Michael Kukulinski

Conclusion:
LD_{50} (Males, Females, and combined): $LD_{50} > 5.0$ g/kg
Toxicity Category: IV (i.e., $LD_{50} > 5.0$ g/kg)
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations: None

Testing Facility: Tox Monitor Laboratories, Inc.
33 West Chicago Avenue
Oak Park, Illinois 60302

Test Material: Maquat 86-M, Lot #MRI83D, a clear liquid

Test Animal:
Rat, Sprague-Dawley derived, albino
Age: 6 to 10 weeks
Weight: 225 to 290 grams
Source: Harlan Sprague Dawley – Indianapolis, Indiana

Test Method: One dosage – 5.0 g/kg – of the undiluted test substance was administered orally by dosing cannula, in single doses to fasted healthy rats, 5 per sex. Clinical observations were conducted daily for the 14-day observation period. Body weights were recorded prior to dosing, and on Days 7 and 14. All animals were sacrificed at the end of the observation period and were subject to gross necropsy.

Results and Discussion: There was no mortality. Therefore, the LD_{50} was observed to be greater than 5.0 mg per kilogram body weight. This places the test substance in Category IV for acute oral toxicity. Clinical signs and necropsy findings were unremarkable. All animals gained weight between Days 0 and 7 and between Days 7 and 14.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Reviewer: W. Powell
Product No.: 10324-85
DP Barcode: D240997
MRID No.: 444063-02
Report No.: TM Study 97-99-4
Study Completion: 07/22/97
Study Director: Michael Kukulinski

Conclusion:
LD_{50} (Males, Females, and Combined): $LD_{50} > 2.0$ g/kg
Toxicity Category: III or IV (i.e., $LD_{50} > 2.0$ g/kg). Category III (defined as 2.0 g/kg < $LD_{50} \leq 5.0$ g/kg) is being assigned for labeling purposes.
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations: None

Testing Facility: Tox Monitor Laboratories, Inc.
33 West Chicago Avenue
Oak Park, Illinois 60302

Test Material: Maquat 86-M, Lot #MRI83D, a clear liquid

Test Animal:
Rabbit, New Zealand White, albino
Age: 8 to 12 weeks
Weight: 2050 to 2190 grams
Source: Kuiper Rabbitry – Gary, Indiana

Test Method: A dose of 2.0 g/kg of the undiluted test material was applied to the dorsal and trunk area of 5 rats per sex and was covered with gauze held in place by a wrapping of plastic sheeting and non-irritating tape. (A call was placed to the testing lab to clarify where the test article was applied on the animals' bodies; an answer was Faxed by the lab on 03/18/98.) This dressing was removed after a 24-hour exposure period, and remaining test article was wiped from the site. The animals were observed for signs of toxicity frequently during the day of dosing and daily for 14 days. A gross necropsy was performed on all animals. Body weights were recorded prior to dosing and on Days 7 and 14.

Results and Discussion: There was no mortality. Therefore, the LD_{50} was observed to be greater than 2.0 g per kilogram body weight. This places the test substance in Category III or IV for acute dermal toxicity; Category III is assigned for labeling purposes. Clinical signs were limited to the presence of

erythema and edema (present on days 1 and 2 only). Necropsy findings were unremarkable. All animals gained weight between Days 0 and 7 and between Days 7 and 14.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4)

Reviewer: W. Powell
Product No.: 10324-85
DP Barcode: D240997
MRID No.: 444063-03
Report No.: TM Study 97-99-1
Study Completion: 07/10/97
Study Director: Michael Kukulinski

Conclusion:
Toxicity Category: IV (i.e., minimal effects, clearing in less than 24 hours)
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations: None

Testing Facility: Tox Monitor Laboratories, Inc.
33 West Chicago Avenue
Oak Park, Illinois 60302

Test Material: Maquat 86-M, Lot #MRI83D, a clear liquid

Test Animal:
Rabbit, New Zealand White, albino
Age: 8 to 10 weeks
Weight: 2005 to 2110 grams
Source: Kuiper Rabbitry – Gary, Indiana

Test Method: 0.1 ml of the undiluted test substance was instilled into the conjunctival sac of one eye of each of six healthy rabbits pre-screened for eye abnormalities. The other eye was untreated and served as a control. Eyelids were held together for about 1 second. The treated eyes were never rinsed. Ocular irritation was evaluated in accordance with the Draize method at 1, 24, 48, and 72 hours after dosing, using a high-intensity white light. Fluorescein dye and ultraviolet light were employed to reveal possible corneal injury beginning with the 24-hour observation.

Results and Discussion: No corneal or iridial involvement was observed. 'Positive' degree of conjunctival involvement (chemosis, grade 2 on the Draize scale) was observed in 2/6 animals, at Hour 1 only. Therefore, the test substance is placed in Toxicity Category IV for primary eye irritation (i.e., minimal effects, clearing in less than 24 hours).

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (§81-5)

Reviewer: W. Powell
Product No.: 10324-85
DP Barcode: D240997
MRID No.: 444063-04
Report No.: TM Study 97-99-2
Study Completion: 07/11/97
Study Director: Michael Kukulinski

Conclusion:
Toxicity Category: IV (i.e., mild or slight irritation)
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations: None

Testing Facility: Tox Monitor Laboratories, Inc.
33 West Chicago Avenue
Oak Park, Illinois 60302

Test Material: Maquat 86-M, Lot #MRI83D, a clear liquid

Test Animal:
Rabbit, New Zealand White, albino
Age: Approximately 8 to 10 weeks
Weight: 2010 to 2120 grams
Source: Kuiper Rabbitry – Gary, Indiana

Test Method: 0.5 ml of the undiluted test substance was applied to the side of the trunk of each of 6 male rabbits, on a 6 cm^2 area from which the hair had been clipped the previous day. (A call was placed to the testing lab to clarify where the test article was applied on the animals' bodies; an answer was Faxed by the lab on 03/18/98.) This site was then occluded. After a 4 hour exposure period, the dressings were removed and excess test material was removed. The test sites were then observed for dermal effects at approximately ½ hour after removal of the dressing, and at approximately 24, 48, and 72 hours after the beginning of the exposure period. Severity of erythema and edema was scored in accordance with the Draize criteria.

Results and Discussion: No edema was observed. Erythema was very slight (grade 1 on the Draize scale) and was observed only at the initial observation time (½ hour after removal of the dressing). This places the test material in Toxicity Category IV for primary dermal irritation.